

REMARKS

Claims 1-19 are pending in this application. Claims 1-19 were rejected under 35 U.S.C. § 112, second paragraph. Claims 1-2, 4-12 and 14-19 were rejected under 35 U.S.C. § 102(b). Claims 1-19 were rejected under 35 U.S.C. § 103. Claim 1 was objected to.

By this amendment, claims 3 and 4 have been canceled, claim 1 has been amended without prejudice or disclaimer of any previously claimed subject matter. Support for the amendments can be found, *inter alia*, throughout the specification, for example, in original claims 3 and 4.

The amendments are made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

Rejection under 35 U.S.C. §112, second paragraph

Claims 1-19 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse this rejection.

Although Applicants believe that the claims were sufficiently definite when considered in view of the specification and the understanding of those of skill in the art, Applicants have attempted to respond to the concerns of the Examiner in order to enhance clarity and to facilitate disposition of the present case.

With regard to claim 2, the Examiner states that the term “the best” is not defined by the claim. Applicants respectfully submit that “the best” is used in the context of the phrase “the best corrected visual acuity.” “Best corrected visual acuity” is a term of art and used as a standard when visual acuity is determined. Applicants describe a procedure for determining the best corrected visual acuity of a patient in Example 1 (pages 35-38). Thus, one skilled in the art would understand the phrase and its use does not render claim 2 indefinite.

With regard to the term “disc area,” Applicants respectfully submit that the term is an art-used unit of measure for the size of the CNV lesion. The phrase “about 4-5 disc areas” thus provides a description of the lesion size. The specification describes that “lesion size is calculated in terms of “Disc Areas (DA) with is a number corresponding to the entire area of a lesion” at page 9. Applicants also describe a procedure for determining the size of the CNV lesion in terms of “disc areas” in Example 2 (pages 38-43). Thus, one skilled in the art would understand the term and its use does not render the claims indefinite.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

Claim Objection

Claim 1 was objected to because of an informality. With the amendment to claim 1, the grammatical error was corrected. Accordingly, Applicants respectfully request withdrawal of the objection.

Rejection under 35 U.S.C. §102

Claims 1-2, 4-12 and 14-19 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Levy *et al.* (U.S. Patent 5,798,349; “Levy”). Applicants respectfully traverse this rejection.

The instant invention is based on Applicants discovery that photodynamic therapy (PDT) is particularly effective for treating occult choroidal neovascular (CNV) lesions in a subgroup of patients. As noted in the specification, this result was surprising since “there was no reason to anticipate this differential pattern of response to PDT.”¹ The claimed invention is directed to a method of treating an occult CNV lesion by providing PDT to a subject assessed as having a small lesion and/or poor visual acuity.

For a claim to be anticipated by a reference, the reference must teach each and every element of the claim. Levy describes treatment of unwanted CNV using PDT. However, Levy does not describe determining visual acuity of the subject or lesion size prior to PDT. The Examiner acknowledges in the 35 U.S.C. §103 rejection that “Levy fails to specifically disclose the visual acuity of subject at baseline to be less than 65 letters.” Office Action, page 5. Also, Levy does not describe the use of PDT with an occult CNV lesion.

Accordingly, Applicants respectfully submit that Levy does not anticipate the claimed invention.

Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §102(b).

Rejection under 35 U.S.C. §103

Claims 1-19 were rejected under 35 U.S.C. §103 as allegedly unpatentable over Levy. Applicants respectfully traverse this rejection.

A *prima facie* case of obviousness requires that three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally,

¹ Specification, page 5, first full paragraph.

the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20USPQ2d 1438 (Fed. Cir. 1991); MPEP §2143. If any one of these three criteria is not met, a *prima facie* case of obviousness has not been established. As presented herein, Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

As discussed above, Levy does not teach the claimed invention. Further, Levy does not suggest determining visual acuity of the subject or lesion size prior to PDT, much less doing so for a subject with occult CNV. Thus, Levy does not teach or suggest the claimed invention.

Since there is no suggestion of the claimed invention in Levy, the reference provides no motivation for one skilled in the art to modify the teaching therein to arrive at the claimed invention. Further, as noted above and discussed in the specification,² from the state of the art at the time of filing, it is surprising that PDT is effective in treating occult CNV, in particular occult CNV in patient's with small lesions and/or poor visual acuity. Thus, Applicants respectfully submit that there is no motivation in the art for the skilled artisan to modify the teaching of Levy to arrive at the claimed invention.

Still further, given the state of the art, Applicants also submit that one skilled in the art would have no expectation of success in treating occult CNV.

Accordingly, the cited reference does not support *prima facie* obviousness with regard to the claimed invention. Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §103.

² See, for example, specification page 4.

CONCLUSION

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the Examiner is encouraged to contact Applicants' representative at the telephone number below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 273012012500.

Dated: May 5, 2004

Respectfully submitted,

By Karen Zachow
Karen ZachowRegistration No.: 46,332
MORRISON & FOERSTER LLP
3811 Valley Centre Drive, Suite 500
San Diego, California 92130
(858) 720-5191